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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/807,901 | 03/24/2004 | Michael V. Lipoma | 2G02.1-101 | 3984 |
| 23506 | 7590 | 12/11/2007 | EXAMINER | |
| GARDNER GROFF GREENWALD & VILLANUEVA, PC | | | HOUSTON, ELIZABETH | |
| 2018 POWERS FERRY ROAD | | | ART UNIT | PAPER NUMBER |
| SUITE 800 | | | 3731 | |
| ATLANTA, GA 30339 | | | MAIL DATE | DELIVERY MODE |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

| | | |
|-------------------|---------------|--|
| Application No. | Applicant(s) | |
| 10/807,901 | LIPOMA ET AL. | |
| Examiner | Art Unit | |
| Elizabeth Houston | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 August 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12, 19-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 24 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 080904

Todd E. Monahan
SPE 3731

- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application
- 6) Other: _____

/DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of invention I, apparatus, claims 1-12 and 19-22 in the reply filed on 08/29/07 is acknowledged.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p) (4) because reference character "163" has been used to designate both "inclined cam face" and "cooperating inclined face". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 21 is objected to because of the following informalities: "an engaged" in line 7 should be --- and engaged. Appropriate correction is required.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-6, 11 and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6, 8, 10 and 13 of U.S. Patent No. 7,288,102. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims in the application are broader and can be anticipated by the claims in the patent. The patent claims disclose a lancet with a drive mechanism having a spring (cl. 4, 10), a carrier (inherent that something carries the lancet prior to being decoupled), a carrier stop member (cl 1, 8), a lancet stop member (2, 8), a cocking mechanism (cl 4, 10), and an endcap that rotates to adjust penetration depth (cl 6, 13). The lancet is decoupled from the drive mechanism and is inertially propelled after the carrier is stopped (cl. 1, 8).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-7, 10-12, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuzawa (WO 02/054952) (For English translation see US 6,929,650).

8. Fukuzawa discloses a lancing device having a drive mechanism comprising a spring (60) and a carrier (41,42); and a lancet (L) that is decoupled from the drive mechanism and slidably floats relative to the carrier during at least a portion of the lancing stroke (Fig. 8). The carrier engages and drives the lancet through a first portion of the stroke (Fig. 3) and is inertially propelled through a second portion of the stroke (Fig. 8) (C8, L18-50 in US patent). The lancing stroke includes the lancet moving from a retracted position (Fig. 3) to an extended position (Fig. 8), and the drive mechanism is decoupled from the lancet when the lancet is extended. A carrier stop member (towards top of device) limits the travel of the carrier before the lancet reaches the extended position. The carrier stop does not limit the travel of the lancet so that after the carrier is stopped the lancet decouples from the carrier and slides relative to the carrier as it continues moving toward the extended position. A lancet stop (8) limits the travel of the lancet. A sled includes the lancet and is slidably received in the carrier (see pawl 31 in Fig. 5). A cocking mechanism comprises at least one cocking arm (31) extending from

the drive mechanism (when the carrier is attached to the drive mechanism) and an engagement surface to retain the cocking arm in the cocked position (see Fig. 5). A trigger mechanism (76) includes a catch release mechanism to release the carrier. The end cap (10a) rotates to adjust penetration depth and has a plurality of stop surfaces. The contact area where the lancet encounters the endcap can be considered to have more than one surface portion. The term "surface" can be interpreted broadly just as the term "portion" would be. The carrier has a carriage (41, 42) that has a flared proximal portion (see enlarged bore towards middle of carriage).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 8, 9, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuzawa (WO 02/054952) in view of Schraga (US 6,514,270).

11. Fukuzawa discloses all the elements substantially claimed as stated above except the carrier having for one or more wings extending out of the housing.

12. Schraga discloses a lancet device with a wing that extends out of the housing (70). The wing is retracted to arm the device to a cocked position with the carrier in a retracted position (see Fig. 2). The wing has a strut (74) which would extend between

the wing and the carriage (3, disclosed by Fukuzawa) and project through a slot in the housing.

13. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a sliding mechanism into the lancing device of Fukuzawa to enable a user to easily load and cock the lancing device. Schraga discloses that the sliding mechanism is a known technique in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known device that was ready for improvement and the results would have been predictable.

14. Regarding the limitation that the carrier struts engage a stop surface defined by the housing slots before the lancet reaches the extended position, it would have been obvious to one having ordinary skill in the art at the time of the invention to rearrange the location of the stop mechanism on the lancing device. Relocating the stop mechanism from the tip of the device to the location of the wings only requires routine skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh
11/29/07


Todd E. Manahan
SPE 3731